IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
Texarkana Division

CYPRESS HOME CARE, INC.	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No.: _____
	)	
QLARANT INTEGRITY SOLUTIONS, LLC	)	
	)	JURY TRIAL DEMANDED
Defendant.	)	
	)	

COMPLAINT

Plaintiff, Cypress Home Care, Inc. ("Cypress"), by and through its undersigned legal counsel, hereby files this Complaint against Qlarant Integrity Solutions, LLC ("Qlarant"), and in support thereof states as follows:

INTRODUCTION

1.   This is a civil fraud and misrepresentation action against a government contractor for intentionally and repeatedly making false representations about the way it calculated alleged Medicare overpayments to providers.

2.   At all times relevant hereto, Cypress was a Medicare-certified home health provider that provided high quality medical care, such as nursing or therapy services, to elderly and disabled patients in their homes. Many of Cypress' patients were Medicare beneficiaries.

3.   Since 2009, Qlarant, previously known as Health Integrity, LLC ("Health Integrity"), has served as a Unified Program Integrity Contractor (UPIC) for the Centers for Medicare and Medicaid Services (CMS), the government agency responsible for administering

the Medicare program.[1] As a UPIC, one of Qlarant's principal duties is to identify and prevent improper payments to Medicare and Medicaid providers.

4.   One of the ways that UPICs identify allegedly improper Medicare payments is by performing audits of claims previously submitted to Medicare for payment. Due to the large number of claims processed by the Medicare program each year, it is generally not feasible for UPICs to audit individual claims. For this reason, UPICs use statistical sampling techniques to "extrapolate" Medicare overpayments based upon review of a sample of the provider's claims.

5.   In 2010 and 2011, Qlarant performed a post-payment audit of 45 claims previously submitted by Cypress to the Medicare program. Qlarant determined that 43 of the claims under review had been paid in error and, through the use of statistical sampling, extrapolated an alleged overpayment in the amount of $11,531,832. Without extrapolation, the alleged overpayment for the 43 claims denied by Qlarant was $81,074.

6.   Due to a flaw in its sample selection processes, the sampling methodologies relied upon by Qlarant in all of their post-payment audits from approximately 2009 to 2013 were not statistically valid. As a result, Qlarant's extrapolated overpayment determinations during this time period were incorrect and unreliable.

7.   In 2013, Qlarant became aware of the error in its sampling methodologies and corrected its sample selection techniques for existing and future audits. However, the flaw was inherent to the manner in which the samples were produced. Qlarant did not correct the samples used to extrapolate overpayments from audits prior to 2013 and left the flawed extrapolated overpayment determinations in place.

8.   After becoming aware of the error in its sampling methodologies, Qlarant did not take any steps to withdraw its overpayment calculations in prior cases where it had used

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[1] UPICs were previously known as Zone Program Integrity Contractors (ZPICs).

statistically invalid sampling methods. In fact, Qlarant continued to defend its extrapolated overpayment determinations from challenges brought by providers in the Medicare administrative appeals process.

9.   Upon receipt of the overpayment determination referenced in paragraph 5, Cypress aggressively contested Qlarant's audit through the available administrative appeals process.

10.   The appeals process took more than six years to complete and caused Cypress to incur considerable fees, costs, and other expenses. Qlarant's allegation that Cypress had received such an astronomical Medicare overpayment destroyed Cypress' reputation and good will in the healthcare community in general and in northeast Texas in particular.

11.   Cypress contested Qlarant's overpayment determination, as affirmed in a final agency decision on behalf of the U.S. Department of Health and Human Services, in the United States District Court for the Eastern District of Texas. On June 11, 2018, the Court reversed the agency's decision upholding the statistical validity of the extrapolation. *See Cypress Home Care, Inc. v. Azar*, 326 F.Supp.3d 307 (E.D. Tex. 2018).

PARTIES

12.   Plaintiff, Cypress Home Care, Inc., is a corporation organized under the laws of the State of Texas. At the time of the events giving rise to this action, Cypress' principal place of business was located at 301 West First Street, Mount Pleasant, Texas 75455. Cypress' current mailing address is P.O. Box 2284, Mount Pleasant, Texas 75456.

13.   Defendant, Qlarant Integrity Solutions LLC, is a limited liability company organized under the laws of the State of Maryland with its principal place of business located at

28464 Marlboro Avenue, Easton, Maryland 21601.[2]

JURISDICTION AND VENUE

14.   The Court has jurisdiction over this action pursuant to 28 U.S.C. §1332.

15.   Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b)(2).

OVERVIEW OF STATISTICAL SAMPLING

16.   Basic principles of statistical sampling are set forth in a number of textbooks, learned treatises, and scholarly articles, including but not limited to *Sampling Techniques* by William Cochran and *Survey Sampling* by Leslie Kish.

17.   The creation of any statistically valid sample begins with a "sampling plan" and a "universe." The sampling plan is a detailed description of all the steps that will be used to select the sample from the universe. The universe is the population for which conclusions will be drawn based upon the observations of the individual members, or "sampling units," of the sample.

18.   The two requirements for a sampling plan are that it (1) must pre-date the actual selection of the sample and (2) be consistent with one and only one sample. Both conditions are needed to ensure that the sample will be generated by a random process not subject to human influence.

19.   The sampling plan sets forth certain limiting criteria that will be applied to the universe to produce the "sampling frame," which is the actual subset of the universe from which the sample will be selected. Often, but not always, the sampling frame coincides with the universe.[3]

20.   The sampling plan also defines an ordering of the sampling frame. The sampling

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[2] Starting with its formation in 2005, Qlarant was initially known as Health Integrity, LLC. On 02/23/18, Qlarant submitted articles of amendment to the State of Maryland to change its name to Qlarant Integrity Solutions, LLC.
[3] This is true for the instant case, where the sampling frame coincided with the universe.

frame must be placed in this order prior to sample selection because different orders will yield different samples.

21.   The sampling units are chosen from the frame through the use of a computer program, such as software developed by the SAS Institute, Inc. The general term for computer programs of this sort is random number generator (RNG). Any computer program, whether an RNG or not, operates by updating an internal state through a sequence of discrete steps. On the first call to the program, this internal state must be initialized, either by the program itself or by the user of the program. In order to allow its output to be replicated, a random number generator allows the user to initialize its internal state by supplying an integer value called a "seed." The seed uniquely determines the sequence of random numbers output by the program. Therefore, if the random number generator is used to select two different samples and is initialized with the same seed value both times, then the exact same sequence of random numbers will be used to perform each selection. A consequence of this improper method is that the two samples will not be statistically independent.

22.   In some cases, even though only one sample is used for extrapolation, two samples are selected with the second sample being used as a reserve sample in case there is a problem with one or more sampling units in the first sample that prevents them from being used for extrapolation.[4]

23.   A statistician can select a reserve sample in different ways, Relevant here, a reserve sample can be selected from the first sample. The units remaining in the first sample after selection of the second sample are then used for extrapolation. When this method is used, the selection of the second sample will alter the composition of the first sample. Because of this, care must be taken that the second sample is selected independently (i.e., with a different seed value)

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[4] Qlarant selected a reserve sample in this case.

of the first sample because, if it is not, the first sample will not be a simple random sample even if it was one prior to selection of the second sample.

24.   Once the sample is constructed, each unit is evaluated according to the design and purpose of the experiment. The findings in the sample are then projected or "extrapolated" to the population.

25.   There are many different types of sample designs that statisticians can use for statistical sampling. The most common sample designs are simple random sampling and stratified random sampling.

26.   A simple random sample is a sample whereby the sampling units are selected without replacement from the frame. The method used for selecting the units must ensure that each distinct sample has the same probability of selection as every other sample. *See, e.g.,* William G. Cochran, *Sampling Techniques* 18 (John Wiley & Sons, eds., 3d ed. 1977).

27.   Irrespective of the sample design chosen by a statistician, the resulting sample must be a probability sample. A probability sample is characterized by two indispensable features: (1) each distinct possible sample that the methodology is capable of selecting must have a known probability of selection; and (2) each sampling unit in each distinct possible sample must also have a known probability of selection. *See, e.g.*, *Sampling Techniques* at 9.

28.   Despite its grammatical form, the term "probability sample" does not refer to an individual sample or even to a sampling methodology but rather to a property of the sampling methodology.

29.   The term "probability sample" is synonymous with the term "statistically valid random sample."

FACTUAL BACKGROUND

30.   At all times relevant hereto, Qlarant, formerly known as Health Integrity, was a UPIC (previously a ZPIC) whose jurisdiction included the State of Texas.

31.   Qlarant is compensated for its work as a UPIC under a contractual arrangement with CMS and has the opportunity to earn all or part of an allotted "award fee" based on CMS' evaluation of the contractor's performance. The base period of each UPIC contract is generally one year, but CMS may choose to extend the duration of the contract for up to four "option years" based on its assessment of the UPIC's performance.

32.   At all times relevant hereto, Cypress was a Medicare-certified home health provider with its principal office located in Mount Pleasant, Texas.

33.   On August 23, 2010, Qlarant requested records in support of 45 home health claims billed by Cypress to the Medicare program in 2008 and 2009. Cypress complied and produced the documentation.

34.   In a letter dated December 20, 2011, Qlarant informed Cypress that it had determined that 43 of the 45 claims reviewed did not meet Medicare criteria for coverage and payment. Qlarant further asserted that the claims it reviewed constituted a "statistically valid random sample" of Cypress' Medicare claims and thereby extrapolated an alleged overpayment in the amount of $11,531,832.

35.   Included with the December 20, 2011 letter was a one-page summary of the sampling methodology employed by Qlarant. The title of this document was "Medicare Sampling Methodology for Simple Random Sample." Qlarant did not include any other materials related to the sampling methodology, such as the seed value, random numbers, or sampling frame, with the audit determination it initially sent to Cypress.

36.   Upon receipt of Qlarant's audit determination, Cypress availed itself of the Medicare administrative process to contest the overpayment assessment. The decisions rendered following the first two levels of review were partially favorable and resulted in a reduction of the extrapolated overpayment to $6,971,723.[5] Cypress thereafter filed a request for a hearing before an Administrative Law Judge (ALJ).

37.   On August 15, 2014, the ALJ to whom the case was assigned contacted Qlarant to request copies of the sampling materials. Qlarant responded and sent the documentation to the ALJ and Cypress.

38.   Relevant here, the sampling materials revealed the process through which Qlarant selected the sample of claims it used for extrapolation. Qlarant did this in two steps. First, Qlarant selected 50 claims from the universe to serve as the sample of claims. Second, Qlarant identified 5 claims in the sample of 50 to set aside as a reserve sample. The sample used for extrapolation therefore included 45 claims.

39.   Qlarant used a software program called SURVEYSELECT, which was created by the SAS Institute, Inc., to generate the random numbers used for its sample selection process. Qlarant used the same random number seed, 072610, to initialize the SURVEYSELECT routine to generate random numbers for both of the steps of the sample selection procedure.

40.   On October 20, 2014, the ALJ conducted a pre-hearing conference in which Qlarant participated. The ALJ directed the parties to submit pre-hearing briefs addressing, among other topics, the validity of the statistical sampling methodology.

41.   On November 19, 2014, Ross Mitchell Cox, Ph.D. ("Dr. Cox") submitted a report on behalf of Cypress to the ALJ in which he concluded that Qlarant's sampling methodology

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[5] The appeal decisions were partially favorable in that they overturned some of the initial claim denials but left all other aspects of the overpayment determination, including the extrapolation, intact. It was therefore Qlarant's responsibility to recalculate the extrapolated overpayment based on the revised claim decisions.

was statistically invalid. More specifically, Dr. Cox asserted that the sample did not meet the requirements for a probability sample or a simple random sample. Dr. Cox mathematically proved these assertions in his report.

42.   In the course of his review of Qlarant's sampling materials, Dr. Cox found and mathematically demonstrated that the selection probabilities of the distinct samples from the universe were not equal but instead differed from one another by a factor of more than 2.1 million. Dr. Cox included as an appendix to his report a series of mathematical proofs that showed the selection probabilities of potential samples were unequal.

43.   On November 21, 2014, Qlarant submitted a report to the ALJ authored by its chief statistician, Aimee Mason, MS ("Ms. Mason"). This report consisted of mostly boilerplate text, which, upon information and belief, Qlarant simply duplicates from case to case. Ms. Mason's report did not address Dr. Cox's findings.

44.   On April 1, 2015, the ALJ conducted an evidentiary hearing. Cypress and Qlarant were represented by legal counsel. Dr. Cox testified as to the statistical issues on behalf of Cypress. Ms. Mason and another statistician, Alan Kvanli, Ph.D. ("Dr. Kvanli"), testified at the direction and on behalf of Qlarant. All witness testimony was made under oath and subject to penalty of perjury.

45.   Ms. Mason's testimony on behalf of Qlarant included the following false statements:

- "This case did involve a simple random sample…and the sample was randomly selected…"

- "Every sample of 45 claims has the same chance of selection despite Dr. Cox's assertions to the contrary."

- "The probability of ending up with this sample is the same as any other sample, in particular the sample of 45 claims used by [Qlarant] actually in this

extrapolation."

- "Again, as I said earlier, every sample of 45 claims has the same chance of selection."

- "The probability of ending up with this sample is the same as any other sample."

46.   Dr. Kvanli's testimony on behalf of Qlarant included the following false statements:

- "I would maintain that, prior to sample selection, every sample of 45 [claims] has the same chance of being selected."

- "I simply maintain that every sample of 45 claims had the same chance [of selection] despite his [Dr. Cox's] argument."

- "This is a random sample, in my opinion, because every sample of 45 [claims] prior to the selection had the same chance of being selected."

47.   The statements by Ms. Mason and Dr. Kvanli summarized in paragraphs 45 and 46 involve questions of mathematics that are subject to proof. As a result, it is possible to mathematically demonstrate that the testimony given by Ms. Mason and Dr. Kvanli was false.

48.   Despite their testimony, neither Ms. Mason nor Dr. Kvanli ever identified an error in the calculations set forth in Dr. Cox's report. Similarly, they did not proffer calculations of their own purporting to show the selection probabilities of the distinct samples were equal or that they knew the selection probabilities of the distinct samples.

49.   Following the ALJ hearing, Cypress continued to challenge the overpayment determination. The agency's final decision was partially favorable in that although it upheld the use of extrapolation, it further reduced the overpayment to $4,314,393.[6]

50.   On June 24, 2016, Cypress filed suit in United States District Court for the Eastern District of Texas contending that the agency's final decision was not supported by

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[6] Qlarant was responsible for recalculating the extrapolated overpayment based on the final agency decision.

substantial evidence and incorrectly applied the relevant legal standards.

51.   On June 11, 2018, the Court issued a decision in which it concluded, among other things, that substantial evidence did not support the use of extrapolation to calculate the alleged Medicare overpayment to Cypress.

COUNT I – FRAUD

52.   Plaintiff hereby incorporates by reference paragraphs 1 through 51 herein.

53.   To assert a claim for fraudulent misrepresentation under Texas law, a plaintiff must demonstrate: (1) a material representation or omission was made; (2) the representation was false; (3) when the representation was made, the speaker knew it was false or made it recklessly without any knowledge of the truth and as a positive assertion; (4) the speaker made the representation with the intent that the plaintiff act upon it; (5) the plaintiff acted in reliance on the representation; and (6) the plaintiff thereby suffered injury. *See Central Petroleum Ltd. V. Geoscience Resource Recovery, LLC*, 543 S.W.3d 901, 921 (Tex. 2011).

54.   Qlarant's representations to Cypress, other CMS contractors, and the ALJ that its sample was a probability sample and a simple random sample were material. These representations formed the basis for the UPIC's determination that Cypress had allegedly been overpaid by Medicare in the amount of $11,531,832.

55.   Qlarant's representations regarding its sampling methodology were false. As explained herein, the sample did not have the requisite selection probabilities to be a simple random sample, as Qlarant asserted. Further, Qlarant's failure to inform Cypress of the flaws in its audit and therefore in its overpayment determinations constituted an intentional omission of material fact reasonably relied upon by Cypress to its detriment.

56.   Qlarant's statisticians, Ms. Mason and Dr. Kvanli, hold advanced degrees in

statistics. At the time of the ALJ hearing in 2015, Ms. Mason was Qlarant's chief statistician and Dr. Kvanli was a professor at the University of North Texas. By virtue of their training and experience in statistics, Ms. Mason and Dr. Kvanli would have known that their statements regarding the sampling methodology were false.

57.   As witnesses testifying on behalf of Qlarant, Ms. Mason and Dr. Kvanli functioned as advocates attempting to persuade the ALJ to uphold Qlarant's sampling methodology. Cypress, moreover, relied on Qlarant's assertions regarding its sampling methodology insofar as it devoted substantial resources and time to contesting the overpayment assessment through the administrative process and in federal court.

58.   As a result of Qlarant's misrepresentation that Cypress had been overpaid by more than $11.5 million, Cypress suffered substantial financial losses from which it never recovered. Cypress also expended considerable sums of money in fees, costs, and other expenses challenging the overpayment, which it would not have done if the alleged overpayment had not been extrapolated but based only on the 43 claims reviewed.

<div align="center">COUNT II – NEGLIGENT MISREPRESENTATION</div>

59.   Plaintiff hereby incorporates by reference paragraphs 1 through 58 herein.

60.   To assert a claim for negligent misrepresentation under Texas law, a plaintiff must demonstrate: (1) the defendant made a representation in the course of its business, or in a transaction in which it has a pecuniary interest, (2) the defendant supplied "false information" for the guidance of others in their business, (3) the defendant did not exercise reasonable care or competence in obtaining or communicating the information, and (4) the plaintiff suffered a pecuniary loss by justifiably relying on the representation. *See Fed. Land Bank Ass'n of Tyler v. Sloane*, 825 S.W.2d 439, 442 (Tex. 1991).

61.   Qlarant's representations to Cypress, other CMS contractors, and the ALJ that its sample was a probability sample and a simple random sample were material. These representations formed the basis for the UPIC's determination that Cypress had allegedly been overpaid by Medicare in the amount of $11,531,832.

62.   Qlarant's representations regarding its sampling methodology were false. As explained herein, the sample did not have the requisite selection probabilities to be a simple random sample, as Qlarant asserted. Additionally, Qlarant made the misrepresentations in the course of its business as a UPIC and in a transaction in which it has a pecuniary interest, as it is compensated as a government contractor for its audit work.

63.   Qlarant's failure to inform Cypress of the flaws in its audit and therefore in its overpayment determinations constituted an omission of material fact reasonably relied upon by Cypress to its detriment.

64.   Qlarant's statisticians, Ms. Mason and Dr. Kvanli, hold advanced degrees in statistics. At the time of the ALJ hearing in 2015, Ms. Mason was Qlarant's chief statistician and Dr. Kvanli was a professor at the University of North Texas. By virtue of their training and experience in statistics, Ms. Mason and Dr. Kvanli should have known that their statements regarding the sampling methodology were false.

65.   As witnesses testifying on behalf of Qlarant, Ms. Mason and Dr. Kvanli functioned as advocates attempting to persuade the ALJ to uphold Qlarant's sampling methodology. Further, Cypress relied on Qlarant's assertions regarding its sampling methodology insofar as it devoted substantial resources and time to contesting the overpayment assessment through the administrative process and in federal court.

66.   As a result of Qlarant's misrepresentation that Cypress had been overpaid by

more than $11.5 million, Cypress suffered substantial financial losses from which it never recovered. Cypress also expended substantial sums of money in fees, costs, and other expenses challenging the overpayment, which it would not have done if the alleged overpayment had not been extrapolated but based only on the 43 claims reviewed.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court:

67.   Enter judgment in Plaintiff's favor;

68.   Award Cypress compensatory damages of at least $2,000,000.

69.   Award Cypress punitive damages in an amount to be determined by the factfinder.

70.   Award Cypress pre- and post-judgment interest along with any and all costs and attorneys' fees for this action as allowed under applicable law; and

71.   Grant Cypress such other relief both at law and equity that it may show itself justly entitled.

Dated: March 29, 2019   Respectfully Submitted,

                                                         /s/ Jeffrey G. Hamilton
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